REMARKS

Applicant respectfully requests reconsideration of the present application in view of the foregoing amendments and these comments.

Status of Claims

Claims 64 and 71 are revised presently, claims 77, 78, and 80 are cancelled, and claims 93 – 96 are added, all without impermissible introduction of new matter. Claims 79 and 81 – 92 stand withdrawn. Upon entry of this response, therefore, pending claims 64, 66, 67, 69 – 76, and 93 – 96 will be under consideration.

Indefiniteness Rejection

The examiner has rejected claim 71, citing MPEP § 2173.05(c). To address the examiner's concern, applicant has amended claim 71 to eliminate the objectionable "preferably" clauses, presently removed to separate dependent claims 93 – 96. Reconsideration and withdrawal of this rejection are requested, therefore.

Obviousness Rejection

In this regard, the examiner has stated that the "instant claims are directed to [a] composition comprising a combination of 1-glyceryl monocaprylate," *a/k/a* glyceryl-1-octanoate, "and niacinamide" (action at page 6, first full paragraph). This statement recalls applicant's response to a previous election-of-species requirement, when applicant identified "(a) 1-glyceryl-monocaprylate, (b) niacinamide, and (e) topical administration" (response dated 20 March 2008, at page 7, second paragraph), upon which the elected claims were deemed to read.

In consideration of the elected species, the examiner has rejected claims 64, 66, 67, and 69 - 76 over the combined disclosures in U.S. patent No. 5,759,584 (Traupe) and the 1995 article of Shalita et al. Traupe is cited for teaching "the treatment of blemished skin, mild forms of acne, and Propionibacterium acnes" with a topical formulation comprising (I) a naturally occurring mixture of wool wax acids or a mixture of wool wax acids processed by distillation and (II) a monoglycerol monocarboxylic acid monoester, such as glycerol

monocaprylate (action at page 6, second paragraph). The Shalita article is invoked for disclosing treating acne vulgaris through the use of nicotinamide.

According to Shalita, the "precise mechanism(s) by which nicotinamide exerts a therapeutic effect in acne vulgaris is unclear," although it "may exert an anti-inflammatory action through inhibition of mast cell histamine release," *inter alia* (page 436, last full paragraph). On the other hand, Traupe says nothing about treating inflammation, *per se*, but instead indicates a focus on "bacterial secondary infections [that] are of etiological importance to blemished skin" (column 1, lines 19 & 20).

Thus, Traupe implicates antimicrobial principles in treating microbe-associated skin conditions, such as acnes caused by Propionibacterium. As the examiner herself recognizes, by contrast, Shalita teaches that "nicotinamide gel is a desirable alternative treatment for acne vulgaris because antimicrobials ... are associated with resistant microorganism[s] such as Proprionibacterium" (action at page 7, second paragraph). Accordingly, it would run contrary to the central purpose of Shalita's disclosure to bring nicotinamide together an active agent, such 1-glyceryl monocaprylate, that is known to "display an antimicrobial action," per Traupe (column 3, last paragraph), even as to Propionibacterium.

Pursuant to MPEP § 2143.01 (V), a sustainable obviousness rejection cannot be founded on a "proposed modification" that would render "the prior art unsatisfactory for its intended purpose." *See, e.g., In re Gordon*, 733 F.2d 900 (Fed Cir 1984) (modifying prior-art strainer by turning it upside-down held incompatible device's gravity-activated operation; hence, impermissible under Section 103). *See also In re Ratti*, 270 F.2d 810, 813 (CCPA 1959) (suggested combination of references disallowed for "require[ing] a substantial ... change in the basic principle under which the [primary reference] construction was designed to operate"). By the same token, it is improper to ground the presently alleged *prima facie* case on the asserted combination of prior art when one reference, Shalita, eschews "antimicrobials" and the other reference, Traupe, heralds the use of an agent that displays "antimicrobial action."

For this reason alone, the pending obviousness rejection should be reconsidered and withdrawn. Applicant would emphasize further, however, that an important aspect of his

claimed invention is the fact that a "combination of fatty acid esters of polyhydroxyalkanes and pyridine carboxy derivat[ives] is unexpectedly effective in suppressing hypersensitivity and inflammatory reactions." Data to this effect appear in the specification at Example 111, for instance, where the

> ...objective ... was to assess the therapeutic value of combining the [aforementioned] two types of active entities ... of the invention.... If the effect of the [combination] is higher than the sum of the components the effect is [deemed] synergistic.

US 2006/0069131 (published version of present application), at paragraph 0176.

Illustrative in this regard were the results obtained with "Compound 51," combining glyceryl octanoate (glyceryl monocaprylate) and nicotinamide (see US 2006/0069131 at paragraph 0177 and in table under paragraph 0163, entry for "Example 51"). As stated in paragraph 0196,

> Compound 51 yielded a statistically significant and dose dependent inhibition of ear oedema comparable to the effect of betamethasone 17-valerate, which was applied at the maximal human clinical dose. This level of efficacy for compound 51 is convincing, since betamethasone 17-valerate is one of the strongest topical steroids on the market. Furthermore, the result indicates a significant synergistic effect of the complex of the invention, since the antiinflammatory effect was 65% higher than the additive effect of the individual active components of the complex. This finding is very surprising and explains how it is possible to obtain an antiinflammatory effect comparable to a strong steroid with substances that are virtually non-toxic and do not induce any of the damaging effects to the skin caused by corticosteroids like betamethasone 17-valerate.

See also Example 112, pages 16 and 17 of US 2006/0069131, especially at paragraphs 0199 and 0217.

These results underscore the patentability of the claimed invention, vis-à-vis the posited Traupe/Shalita combination, that the internal inconsistency of that combination already establishes, as demonstrated above. See also MPEP § 2142 (applicant may invoke evidence of unexpected results drawn from original specification). Applicant submits, therefore, that the present application is in condition for allowance.

CONCLUSION

In view of the foregoing, favorable reconsideration of this application is respectfully requested. Also, Examiner Karol is invited to contact the undersigned directly, should she feel that any issue warrants further consideration.

The Commissioner is hereby authorized to charge any additional fees, which may be required under 37 C.F.R. §§ 1.16-1.17, and to credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment accompany this response, then the Commissioner is authorized to charge the unpaid amount to the same deposit account. If any extension is needed for timely acceptance of submitted papers, then Applicant hereby petitions for such extension under 37 C.F.R. § 1.136 and authorizes payment of the relevant fee(s) to the deposit account.

Respectfully submitted,

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